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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,632	04/07/1999	PETER MICHAEL WATERHOUSE	021565-060	6526

21839 7590 06/22/2006

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EXAMINER

ZARA, JANE J

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/287,632	<b>Applicant(s)</b> WATERHOUSE ET AL.	
	<b>Examiner</b> Jane Zara	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 5-10-06.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10,12,22,26,40-44,46,50,53,54,56,58 and 63-108 is/are pending in the application.
- 4a) Of the above claim(s) 1-10,12,40,43,44,46,50,70-84,98,99 and 104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,26,42,53,54,56,58,63-69,85-97,100-103 and 106-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office action is in response to the communication filed 5-10-06.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

This application contains claims 1-10, 12, 40, 43, 44, 46, 50, 70-84, 98, 99, 104 and 104 drawn to an invention nonelected with traverse in Paper No. 12-3-04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Response to Arguments and Amendments***

#### ***Withdrawn Rejections***

Any rejections not repeated in this Office action are hereby withdrawn.

#### ***Maintained Rejections***

Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 85-97, 100-103 and 106-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed 11-10-05 and for the reasons set forth below.

The claims are drawn to plant cells, plants and nucleic acid constructs comprising chimeric DNA that, when transcribed, yields RNA comprising two annealing

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RNA strands, one of which comprises a sense strand comprising at least 10, 20 or 50 consecutive nucleotides having between 95-100% sequence identity with the sequences of a target gene of interest, and which chimeric DNA further encodes an annealing antisense sequence having 95-100% sequence identity with the sense strand, and which nucleic acid construct further comprises any intron sequence which is heterologous to the sense strand, and which intron is optionally between the sense and antisense strands.

The specification and claims do not adequately describe the broad genus comprising chimeric DNA that, when transcribed, yield two annealing RNA strands sharing between 95-100% sequence identity with any target gene of interest and which further comprise any intron sequence heterologous to the sense strand. The genus claimed embraces a myriad of sequences which have not been adequately described or represented by a representative number of species. The specification teaches fully complementary pair constructs for reducing the phenotypic expression of a transgenic Gus gene (of approximately 1580 base pairs), and complementary pair constructs for reducing the phenotypic expression of the  $\Delta 12$  desaturase target gene in *Arabidopsis* (of approximately 620 base pairs) which complementary pair constructs additionally comprise the pyruvate orthophosphate dikinase 2 intron 2 from *Flaveria trinervia* (SEQ ID NO. 7). The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between members of this very broad is permitted. The specification fails to teach or adequately describe a representative number of species in the genus such that the common

attributes or characteristics concisely identifying members of the proposed genus are exemplified. And because the genus claimed is so highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the broad genus claimed. Thus, Applicant was not in possession of the claimed genus.

Applicant's arguments filed 5-10-06 have been fully considered but they are not persuasive. Applicant argues that the instantly claimed invention is unlike one drawn to an enzyme, whose function relies upon tertiary structural integrity that might lose function upon variation in sequences. Applicant also argues that the recited degree of similarity to a target gene is within a range which reasonably correlates with the function of the instantly claimed constructs. Applicant also asserts that both general teachings and specific examples have been provided for the production of the claimed chimeric genes in the instant disclosure.

Applicant is correct that the instant constructs are not encoding enzymes whose function could be abolished or at least compromised by slight or subtle sequence changes. The specification discloses the targeting and inhibition of expression of a transgenic Gus gene (of approximately 1580 base pairs) using fully complementary pair constructs, as well as disclosing complementary pair constructs for reducing the phenotypic expression of the  $\Delta 12$  desaturase target gene in *Arabidopsis* (of approximately 620 base pairs) which complementary pair constructs additionally comprise the pyruvate orthophosphate dikinase 2 intron 2 from *Flaveria trinervia*. Contrary to Applicant's assertions, these examples and general teachings are not

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representative of the broad genus of compounds claimed, comprising siRNA with at least 95% complementarity to any target gene of interest and further comprising any intron which is heterologous to the sense strand sequence, which comprises at least 95% complementarity to any target gene. The examples provided, both generally and specifically, are not representative of the broad genus of compounds or constructs claimed, and which provide for the unexpected results of enhanced inhibition of expression of any target gene of interest. For these reasons, the rejection for lacking adequate written description is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices

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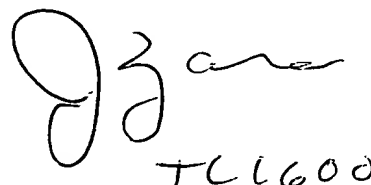
published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**Jane Zara**  
**6-20-06**

JANE ZARA, PH.D.  
PRIMARY EXAMINER



Handwritten signature of Jane Zara, with the initials 'JZ' and the number '761600' written below it.